Message

From: D'Amico, Louis [DAmico.Louis@epa.gov]
Sent: 1/13/2021 2:31:38 PM
To: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]; Hubbard, Carolyn [Hubbard.Carolyn@epa.gov]; Blackburn, Elizabeth [Blackburn.Elizabeth@epa.gov]
Subject: FYI. Inside EPA on PFBS

Nothing really significant here. Just that it went to OIRA review, and that this is different than how IRIS had done things. It notes the assessment is not an IRIS assessment but was managed out of ORD.

https://insideepa.com/daily-feed/epa-sends-pfbs-toxicity-value-oira-review

EPA sends PFBS toxicity value for OIRA review
January 12, 2021
EPA has sent its "Human Health Toxicity Values" for a per- and polyfluoroalkyl substance (PFAS) known as PFBS to the White House Office of Management and Budget (OMB) for regulatory review, signaling the agency will likely finalize risk values for a PFAS intended to replace older substances the agency has phased out.

EPA sent the toxicity values for perfluorobutane sulfonic acid (PFBS) to OMB's Office of Information and Regulatory Affairs (OIRA) for review Jan. 11, according to OMB's website.

The notice indicates EPA is moving toward completion of the toxicity values document, which was first released in draft form in late 2018, along with a similar document for another newer, replacement PFAS known as GenX.

Both toxicity values documents are included in the Trump EPA's PFAS Action Plan.

In the past, EPA has not publicly submitted such toxicity assessments to the White House's OIRA for regulatory review in accordance with Executive Order 12866, though many past Integrated Risk Information System (IRIS) assessments underwent interagency review conducted by OIRA informally during the Bush Administration and OIRA and other agencies provided comments to Obama EPA-era IRIS assessments through an interagency process.

While not technically an IRIS assessment -- the PFBS and GenX evaluations are not included in IRIS' tracking and regular updates on its assessments -- the draft document indicates the PFBS toxicity value was directed and managed by the center within EPA's research and development office formerly known as the National Center for Environmental Assessment, which also houses the IRIS program.

The move follows a December 2019 meeting of the National Drinking Water Advisory Council (NDWAC) where some state officials pressed EPA to go beyond its current plans to craft toxicity values for several PFAS, including PFBS and GenX and instead develop non-binding health advisory levels in drinking water, arguing the toxicity values are of little use to state drinking water and cleanup programs.

But while several state officials at the NDWAC meeting gave different reasons for their calls, an agency official noted that not all states favor development of the health advisories.

Should EPA eventually craft such health advisory levels, it could provide states with clearer -- albeit non-regulatory -- cleanup targets for drinking water contaminated with PFAS, the class of non-stick chemicals that is posing health concerns in communities across the country, than the toxicity values would provide.

EPA released the draft document for PFBS in November 2018 for public comment, along with the draft for GenX, following a letter peer review process. The draft documents contain toxicity values known as reference doses (RfD), or the maximum amount EPA estimates can be ingested daily over a lifetime without incurring a related effect.

As such, the levels do not provide recommended cleanup targets, a difference from the health advisory levels for PFOA and PFOS that the agency proposed in 2016, which set 70 parts per trillion (ppt) as the recommended levels that offers a margin of protection against adverse health effects from a lifetime of exposure.

The draft RfD for PFBS of 1x10^-2 mg/kg-day is weaker than an existing December 2017 assessment conducted by the Minnesota Department of Health of 4.3x10^-4.

PFBS is a replacement chemical for PFOS, which was voluntarily phased out by its U.S. manufacturers as part of the same 2006 phaseout agreement as PFOA. "PFBS has been identified in the environment and consumer products, including surface water, wastewater, drinking water, dust, carpeting and carpet cleaners, floor wax, and food packaging," the agency says.

In its draft assessment of PFBS, EPA describes reports that toxicology studies in "adult and developing rats and mice have been shown to result in thyroid, developmental, and kidney effects."

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